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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHLAPKOHL, WALTER	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,300	PORRO ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	wls

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/30/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the papers filed 10/11/2005. Claims 12-14 are pending.

Election/Restrictions

Receipt is acknowledged of the papers filed 10/11/2005 in which Applicant notes the papers of 6/25/2003 in which claims 1-11 and 15-40 were cancelled and claims 12-14 were amended to recite methods of generating ascorbic acid. All pending claims were therefore directed to a single invention and, as such, the restriction requirement is withdrawn.

Specification

The disclosure is objected to because of the following informalities: Line 30 of page 8 recites "were grown on mineral medium (2% glucose, 0.67% YNB)" and should recite "minimal medium."

Appropriate correction is required.

Information Disclosure Statement

It is noted that references have been submitted on 6/25/2003 and 7/30/2003. However, these references were not listed on a form PTO-1449 or equivalent and have therefore not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 12-14 are drawn to recombinant yeast capable of converting an ascorbic acid precursor into L-ascorbic acid, wherein the yeast is functionally transformed with a set of coding regions encoding L-galactose dehydrogenase (LGDH) of SEQ

ID NO: 11 (amino acid of claims 12-13)/SEQ ID NO: 12 (nucleic acid of claim 14) as well as enzymes/nucleic acids having at least about 90% similarity and/or identity with those sequences. Thus the claims comprise a set of coding regions/amino acids defined by the function of the encoded protein.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification describes one nucleic acid sequence for LGDH and one protein sequence for LGDH wherein both sequences are from *Arabidopsis thaliana* (page 13, lines 10-13). No description is provided of any other LGDH sequences that result in a functionally transformed yeast cell capable of converting an ascorbic acid precursor into ascorbic acid or of any structure or sequence motifs that such LGDH sequences would share.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only representative of one LGDH from one source (*A. thaliana*). The

results are not necessarily predictive of any other LGDH sequence. Thus, it is impossible for one to extrapolate from the one nucleic acid and the one amino acid sequence described herein those sequences that would necessarily meet the structural/functional characteristics of the rejected claims.

The prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set of LGDH enzymes. A review published shortly before the effective date of the instant application describes an L-galactose dehydrogenase discovered in the pea plant and *A. thaliana* as a "newly discovered NAD+-dependent L-galactose dehydrogenase" and further states that the enzyme is "as far as we know, the only plant dehydrogenase acting on a non-phosphorylated sugar" (Smirnoff, N. Ascorbic acid: metabolism and functions of a multi-faceted molecule. *Current Opinion in Plant Biology* (2000) 3:229-236). The review further describes that the enzyme has been purified and cloned but the data is unpublished (page 230, second paragraph).

Given the very large genus of sequences encompassed by the rejected claims, and given the limited description provided by the prior art and specification with regard to their common sequence motifs/structures, the skilled artisan would not have been able to envision a sufficient number of specific

embodiments that meet the functional limitations of the claims to describe the broadly claimed genus of LGDH sequences with 90% identity and/or similarity with SEQ ID NOS: 11 and 12. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those embodiments that satisfy the functional limitations of the claimed genus of LGDH enzymes with regard to their capability to convert ascorbic acid precursors into ascorbic acid as LGDH does. Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 12-14.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-14 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 7 and 11-14 of US Patent Application No. 10/606,302 as follows: instant claim 12 over co-pending claims 7 and 11-12; instant claim 13 over co-pending claims 7, 11 and 13; instant claim 14 over copending claims 7, 11 and 14. Although the conflicting claims are not identical, they are not patentably distinct from each other because an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). The MPEP states, at §804, that

> [t]he specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCOA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-2,

> 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According o the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

With respect to instant claims 12-14, the instant claim in each instance is more narrowly drawn than the co-pending claim. However, the portion of US Patent Application 10/606,302 that supports each of claims 7 and 11-14 defines the patented invention as including embodiments which possess each of the narrower limitations of the instant claims. Thus, the method of instant claims 12-14 are not patentably distinct from that of copending claims 7 and 11-14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in

> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berry et al (US Patent Application Publication No. US2002/0012979 A1, IDS Ref. Des. A1) in view of Obermaier et al (EMBL/GenBank/DDBT Entry O81884, IDS Ref. Des. C3).

Berry et al teach a method of generating L-ascorbic acid with a genetically modified yeast that increases the action of enzymes such as L-galactose dehydrogenase (see page 3, paragraph

0034; page 4, paragraph 0035; page 5, paragraph 0045; page 81, first column; and the abstract). Berry et al also teach the genus *Arabidopsis* as a source for the L-galactose dehydrogenase (see Figure 1C) and cite in this context Wheeler et al's identification of L-galactose dehydrogenase from pea and *Arabidopsis* (Nature (1998) 393:365-369, IDS Ref. Des. C2) in which no sequence information is provided (see paragraph 0041 bridging pages 4-5).

Barry et al do not teach this method specifically for the L-galactose dehydrogenase of SEQ ID NO: 11.

Obermaier et al teach the L-galactose dehydrogenase of SEQ ID NO: 11 from *Arabidopsis thaliana*. The same EMBL/GenBank/DDBT Entry O81884 also teaches that two of the same authors from the Wheeler reference, cited by Berry et al (Wheeler and Smirnoff) submitted the same sequence at a later date.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the L-galactose dehydrogenase sequence as taught by Obermaier et al in the method of generating ascorbic acid as taught by Berry et al because Berry et al teach that it is within the skill of the art to utilize a recombinant yeast transformed with L-galactose dehydrogenase from *Arabidopsis* to generate ascorbic acid and

Obermaier et al teach an L-galactose dehydrogenase sequence from *Arabidopsis thaliana*.

One would have been motivated to use the L-galactose dehydrogenase sequence as taught by Obermaier et al in the method of generating ascorbic acid as taught by Berry et al because, as determined by the O81884 EMBL/GenBank/DDBT record, Obermaier et al's sequence was the only L-galactose dehydrogenase sequence from *A. thaliana* publicly available at the time the claimed invention was made.

Thus, based upon the teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result when utilizing the L-galactose dehydrogenase sequence as taught by Obermaier et al in the method of generating ascorbic acid of Berry et al.

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If

Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view

the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter A. Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

November 27, 2005

JAMES KETTER
PRIMARY EXAMINER